

REMARKS

This paper is being filed in response to the Office Action dated April 14, 2003 that was issued in connection with the above-identified patent application. Applicants also enclose herewith a Petition for Extension of Time pursuant to 37 C.F.R. §1.136(a) and the fee required under 37 C.F.R. §1.17(a)(3). Applicants additionally enclose herewith a Declaration under 37 C.F.R. § 1.132 (hereinafter "Declaration"). Applicants respectfully request reconsideration of the instant application in view of the amendments and remarks presented herein.

Claims 1-6 are pending in the instant application. Claims 1 and 5 have been amended herein. These amendments are supported by the application as originally filed at, inter alia, page 3, lines 16-22 and, therefore, do not constitute new matter. Additional support for these amendments may be found in Applicant's Declaration enclosed herewith.

Applicants thank the Examiner for making himself available for and participating in a telephonic interview with Applicant's Attorney Carmella L. Stephens and Applicant's Agent Guy F. Birkenmeier on August 11, 2003.

Claims Are Patentable Over Brandt

Claims 1, 2, 4, and 5 have been rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Brandt et al., 2001, *J. Virol.* 75(2):850-856 (hereinafter "Brandt"). The Examiner has alleged that Brandt recites a vector comprising a vaccinia virus vector with reduced pathogenicity in an animal host which comprises a deletion in the E3L gene and further comprises exogenous DNA operably linked to expression control elements. *See* Office Action dated April 12, 2002, pages 2-3, bridging paragraph. The Examiner has also alleged that Brandt discloses a method for making a recombinant gene product comprising subjecting said vaccinia

virus vector to conditions whereby the exogenous gene product is expressed. *See Id.* Finally, the Examiner has alleged that Applicant's addition of Teresa Brandt as an inventor is insufficient to remove Brandt as a prior art reference pursuant to 35 U.S.C. § 102(a).

Applicants traverse these rejections and assert that Claims 1 and 5, as amended herein are novel over Brandt. For a reference to anticipate, it must teach each and every limitation of the claims. *See e.g. Structural Rubber Products Co. v. Park Rubber Co.*, 749 F.2d 707, 715-716 (Fed. Cir. 1984). Claims 2 and 4 are dependent on claim 1. Therefore, this rejection will be addressed in terms of independent claims 1 and 5.

Claims 1 and 5, as amended herein, recite "an E3L gene that has a deletion of the region encoding amino acids 184-190 of the E3L protein and **encodes a protein that binds dsRNA...**" *See* claims 1 and 5 (emphasis added). Accordingly, the instantly claimed vectors (a) have an E3L gene (b) that encodes a protein that lacks amino acids 184-190, yet (c) retains the ability to bind dsRNA. Brandt fails to anticipate the instantly claimed invention at least in that it does not teach (c), i.e. an E3L protein capable of binding dsRNA.

The ability of the proteins encoded by E3L genes of the invention to bind dsRNA is taught in the specification as originally filed, *inter alia*, at page 3, lines 16-22. Applicants respectfully invite the Examiner's attention to paragraphs 5-10 of the enclosed Declaration. These paragraphs clearly support the teaching of the specification as filed by showing that E3LΔ7C binds dsRNA. In addition, Applicants respectfully invite the Examiner's attention to Chang et al. (*Virology* 1993; vol. 194, pages 537-547)(made of record by Applicant's IDS filed July 2, 2001 and considered by the Examiner on October 21, 2001), a copy of which is enclosed herewith for the Examiner's convenience. Chang et al. discloses that E3LΔ7C protein binds dsRNA. *See* Chang et al., page, 537, abstract and page 541, col. 2, lines 17-19.

In contrast, Brandt discloses recombinant vaccinia virus having an E3L gene that encodes only amino acids 1-164 (hereinafter "E3LΔ26C"). *See* Brandt, Figure 1. Although Brandt does not disclose whether E3LΔ26C protein binds dsRNA, Applicants respectfully invite the Examiner's attention to the enclosed Declaration under 37 C.F.R. § 1.132 at paragraphs 5-7, which demonstrate that the E3LΔ26C protein of Brandt does not bind any detectable amount of dsRNA. Similarly, Chang et al. discloses that E3LΔ26C protein does not bind dsRNA. *See* Chang et al., page 537, abstract and page 541, col. 2, lines 19-22. Therefore, since Brandt fails to teach each and every limitation of claims 1 and 5, Brandt fails to anticipate the claimed invention. During the telephonic interview on August 11, 2003, Examiner Guzo indicated that the addition of a limitation related to the dsRNA-binding affinity of the 184-190 deletion coupled with evidence that the E3LΔ26C protein does not bind dsRNA would overcome this rejection. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims Are Patentable Over Beattie

Claims 1-5 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Beattie et al., 1996, *Virus Genes* 12(1):89-94 (hereinafter "Beattie"). The Examiner has reasserted this rejection and alleged that Applicants earlier argument that Beattie teaches away from using its vaccinia vector for animal testing is not persuasive. The Examiner has alleged that Beattie does not teach away from using its vector in animal testing. The Examiner further alleges that teaching away from the instant claims is irrelevant to an anticipation analysis.

Applicants traverse this rejection and assert that Beattie fails to teach each and every element of the claimed invention. Claims 2-4 are dependent on claim 1. Therefore, this rejection will be addressed in terms of independent claims 1 and 5. As noted above, these claims

relate to a vaccinia virus vector comprising a nucleic acid sequence that encodes an E3L protein that lacks amino acids 184-190, yet retains the ability to bind dsRNA. Beattie, by contrast, teaches a vaccinia virus vector that does not encode **any** of the amino acids of the E3L gene. *See* Beattie, page 90, col. 2, first paragraph *citing* Beattie et al., 1995, *J. Virol.* 69(1):499-505 (made of record by Applicant's IDS filed August 2, 2001 and considered by the Examiner on October 21, 2001). Thus, the vaccinia virus of Beattie does not encode an E3L protein that binds dsRNA. During the telephonic interview on August 11, 2003, Examiner Guzo acknowledged that a vaccinia virus completely lacking an E3L gene could not encode an E3L protein that binds dsRNA. Therefore, since Beattie clearly fails to teach each and every limitation of claims 1 and 5, Applicants respectfully request withdrawal of this rejection.

Claims Are Patentable Over Jacobs

Claims 1, 3, and 4 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by International PCT Publication WO 99/55910 by Jacobs (hereinafter "Jacobs"). The Examiner has reasserted this rejection and alleged that Applicants earlier argument that Jacobs does not teach a vaccinia virus with reduced pathogenicity in an animal host is not persuasive.

Applicants traverse this rejection and assert that Jacobs fails to teach each limitation of claims 1, 3, and 4. Jacobs teaches vaccinia virus vectors in which the E3L gene have been deleted or inactivated. *See* Jacobs, page 5, lines 6-7. However, Jacobs does not teach a vaccinia virus vector comprising a nucleic acid sequence that encodes an E3L protein that lacks amino acids 184-190, yet retains the ability to bind dsRNA. As the Examiner has acknowledged, a vaccinia virus lacking an E3L gene, can not encode an E3L protein that binds dsRNA.

Therefore, Jacobs fails to teach each and every limitation of claims 1, 3, and 4. Applicants, therefore, respectfully request withdrawal of this rejection.

Conclusion

In summary, Brandt, Beattie, and Jacobs each fail to teach an expression vector comprising an E3L gene encoding a protein that lacks amino acids 184-190, yet retains the ability to bind dsRNA. Therefore, Brandt, Beattie, and Jacobs fail to teach every limitation of the claimed invention. In view of the foregoing remarks, Applicants believe that the claims are in condition for allowance and respectfully request prompt favorable action.

Applicants enclose herewith the fee required under 37 C.F.R. § 1.17(a)(3).

Applicants do not believe that any additional fees are required with this paper. Nevertheless, the Commissioner is hereby authorized to charge any fees occasioned by this submission not otherwise enclosed herewith to Deposit Account No. 02-4377. Please credit any overpayment of fees associated with this filing to the above-identified deposit account. A duplicate of this page is enclosed.

Respectfully submitted,

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Enclosures